

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

ASCENT PHARMACEUTICALS, INC.,

Plaintiff,

v.

MERRICK B. GARLAND, in his official capacity as U.S. Attorney General, UNITED STATES DEPARTMENT OF JUSTICE, UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, ANNE MILGRAM, in her official capacity as Administrator of DEA, TERESA A. WALLBAUM, in her official capacity as an Administrative Law Judge of DEA, and THE UNITED STATES OF AMERICA

Defendants.

Civ. No. 2:23-cv-8260

COMPLAINT

Plaintiff Ascent Pharmaceuticals, Inc. (“Ascent”), for its complaint against Defendants Merrick B. Garland, in his official capacity as Attorney General of the United States, the United States Department of Justice, the United States Drug Enforcement Administration (“DEA”), Anne Milgram, in her official capacity as Administrator of DEA, and the Honorable Teresa A. Wallbaum, in her capacity as an Administrative Law Judge (“ALJ”) of DEA, and the United States of America (collectively, the “Defendants”), hereby alleges, based on knowledge of its own conduct, and on information and belief as to all other matters, as follows:

NATURE OF ACTION

1. This action arises from DEA’s attempt to subject Ascent—a minority-owned pharmaceutical company with no prior history of regulatory infractions—to an unconstitutional administrative proceeding (the “Administrative Proceeding”) before a DEA Administrative Law Judge (“ALJ”). Defendants issued an Order to Show Cause to revoke Ascent’s DEA Certificates

of Registration, compelling Ascent to participate in an unlawful adjudicative process before a DEA ALJ who was appointed in violation of the Appointments Clause of Article II, Section 2, of the Constitution and is not accountable to President, in violation of the Take Care Clause of Article II, Section 3 of the Constitution. Ascent is entitled to injunctive and declaratory relief to prevent the irreparable harm it would suffer if subjected to such an unconstitutional proceeding.¹

2. The United States Supreme Court has found that an ALJ appointment process nearly identical to that used by DEA is unconstitutional. DEA, however, has done nothing to conform its ALJ appointment process to constitutional requirements. Moreover, statutory restrictions on an ALJ's removal violate the President's Article II executive power. DEA nonetheless seeks to compel Ascent to participate in an unconstitutional DEA administrative proceeding. Ascent seeks declaratory and injunctive relief to prevent the irreparable harm it would suffer if subjected to such an unconstitutional proceeding.

3. DEA ALJs are executive "officers" for purposes of Article II's Appointments Clause. They hold continuing positions, established by law, in which they exercise significant authority and discretion presiding over DEA administrative hearings and adjudicating adversarial enforcement proceedings.

4. Under the Appointments Clause, inferior Article II "officers" such as DEA's ALJs must be appointed either by the President or the Head of their Department, the Attorney General of the United States. U.S. Const. art. II, § 2, cl. 2. DEA ALJs, however, are appointed by neither.

¹ Ascent does not move this Court for a preliminary injunction, as the assigned ALJ has indicated her intent to stay the Administrative Proceeding upon the filing of this action and the filing of a stay action in the Administrative Proceeding. If, contrary to the ALJs stated intention, she does not enter a stay until final resolution of this proceeding, Ascent will seek emergency relief in this Court.

On information and belief, the DEA ALJ presiding over Ascent’s administrative hearing was selected from a pool of candidates provided by the White House Office of Personnel Management (“OPM”) and appointed by the DEA Administrator upon recommendation from DEA’s Chief ALJ.²

5. In June 2018, the United States Supreme Court confirmed that this ALJ appointment process is unconstitutional in *Lucia v. S.E.C.*, 138 S. Ct. 2044 (2018). Although the Court’s decision specifically addressed the appointment of ALJs for the Securities and Exchange Commission (“SEC”), its reasoning equally applies to the appointment of DEA’s ALJs. The Solicitor General explicitly acknowledged this fact in a memorandum addressed to all agency general counsels made public following the Supreme Court’s decision in *Lucia*. In that memorandum, the Solicitor General stated that “SEC ALJs, and other ALJs who exercise similar powers, are inferior officers and must be appointed as such.”³

6. The framework for removal of DEA’s ALJs is similarly unconstitutional. Article II vests “[t]he executive Power” in the President, including ultimate authority to remove officers to ensure that the law is “faithfully executed.” U.S. Const. art. II, § 1, cl. 1; *id.* § 3. The Supreme Court has held that, because the executive power is vested in the President, Article II requires

² Pursuant to Federal Rule of Civil Procedure 11(b)(3), any allegations made on information and belief will have additional evidentiary support after a reasonable opportunity for further investigation on discovery. To be clear, however, with respect to ALJ appointments, DEA’s website says simply that ALJs “are appointed for life under the Administrative Procedures Act” It makes no mention of whether ALJs are currently appointed by the Attorney General or an inferior officer. Accordingly, Ascent’s counsel contacted DEA to ascertain who and how ALJ Wallbaum was appointed. Ascent’s counsel were directed to Chambers for the information. An individual assigned to ALJ’s Wallbaum’s Chambers said simply, “we do not give out that information.”

³ Office of the Solicitor General, Guidance on Administrative Law Judges after *Lucia v. SEC* (S. Ct.), (July 23, 2018) *available at* <https://static.reuters.com/resources/media/editorial/20180723/ALJ--SGMEMO.pdf>.

inferior officers, such as ALJs, to be answerable to the President, and not separated from the President by attenuated chains of accountability. *See Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 492-98 (2010) (“*Free Enterprise*”). Statutory prohibitions found in Sections 7521(a) and 1202(d) of Title 5 of the United States Code prevent the President and Attorney General from removing DEA ALJs. Rather, they may be removed only for “good cause” as “determined” by the Merit Systems Protection Board (“MSPB”), whose members themselves can only be removed by the President on certain limited “good cause” grounds. This scheme—creating two layers of “for cause” protection between the President (or Attorney General) and his inferior officer ALJs—deprives the President (or Attorney General) from exercising his executive oversight duties and therefore is violates Article II. *Id.* at 492.

7. This Court offers Ascent its only opportunity for meaningful judicial review that could prevent a deprivation of its constitutional rights. Ascent cannot wait until a DEA ALJ conducts a hearing and reaches a determination before seeking review in an Article III court, because Ascent would then have already suffered a constitutional harm. Ascent thus seeks protection from an “illegitimate proceeding, led by an illegitimate decisionmaker.” *Axon Enter., Inc. v. Fed. Trade Comm’n*, 598 U.S. 175, 191 (2023).

8. Under the Supreme Court’s decision earlier this year in *Axon*, Ascent is entitled to seek relief in this Court now to address its constitutional challenges to avoid compounding the “here-and-now injury” from being subjected to this illegitimate proceeding—a harm that is “impossible to remedy once the proceeding is over, which is when appellate review kicks in.” 598 U.S. at 192.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1346 because this action arises under the Constitution and laws of the United

States concerning commercial regulation. The United States has waived its sovereign immunity from this lawsuit in 5 U.S.C. § 702.

10. Venue is proper in this district under 28 U.S.C. § 1391(e) because (i) one or more Defendants is an officer or employee of the United States or any agency thereof acting in his official capacity or under color of legal authority, or is an agency of the United States, or is the United States and (ii) Plaintiff resides in this District and no real property is involved in the action.

THE PARTIES

11. Plaintiff Ascent is a minority-owned generic drug wholesale manufacturer incorporated in New York with its principal place of business in Central Islip, New York. Founded in 2011, Ascent develops and produces a range of specialty prescription drugs to treat medical conditions including Attention Deficit Hyperactivity Disorder (“ADHD”), cardiovascular and inflammatory symptoms, depression, and pain.

12. The company has invested more than \$200 million in its facilities, good manufacturing practices, and research and development. Approximately 70% of its business concerns the production of Schedule II controlled drugs, and until recently, it produced approximately 20% of the market for generic ADHD medications. The company is registered with DEA under numbers RA0448503 and RA0452095 (the latter being for its analytical laboratory).

13. Defendant Merrick B. Garland is the Attorney General of the United States, and the head and principal officer of the United States Department of Justice. He is sued in his official capacity.

14. Defendant United States Department of Justice is an executive department of the United States, headquartered in Washington, D.C.

15. Defendant DEA is a federal government agency tasked with enforcing the controlled substances laws and regulations of the United States and is headquartered in Virginia.

16. Defendant Anne Milgram is the Administrator of DEA. She is sued in her official capacity.

17. Defendant the Honorable Teresa A. Wallbaum is an ALJ of DEA. She is sued in her official capacity.

18. Defendant United States of America is named in accordance with 5 U.S.C. § 702.

FACTUAL ALLEGATIONS

A. Ascent Annually Applies to the DEA For Quota of Raw Materials

19. DEA regulates controlled substances through the Controlled Substances Act of 1970 (“CSA”), 21 U.S.C. § 801 *et seq.*, as well as regulations it promulgates.⁴ The Attorney General has delegated his regulatory authority under CSA to the Administrator of DEA.⁵

20. The CSA and its implementing regulations authorize DEA to annually determine the aggregate production quotas for each controlled substance listed in Schedule I and Schedule II.⁶ This quota system facilitates accounting and ensures the nation has a sufficient amount of each controlled substance in circulation. This system also simultaneously acts as a preventative measure against diversion by enabling DEA to limit the amount of drugs introduced into the supply chain.

21. The CSA and its implementing regulations also authorize DEA to fix and issue individual procurement and manufacturing quotas—derived from the aggregate production quotas—to each registrant procuring Schedule I or II drugs who submits a yearly application.⁷

⁴ See 21 U.S.C. § 871(b) (creating rulemaking and enforcement authority); 28 C.F.R. § 0.100.

⁵ 28 C.F.R. § 0.100(b); *see also* 21 U.S.C. § 871(a) (permitting delegation).

⁶ 21 U.S.C. § 826(a); 21 C.F.R. § 1303.11.

⁷ 21 U.S.C. § 826(b); 21 C.F.R. § 1303.12.

The quota authorizes the registrant to procure a specific quantity of raw materials for manufacturing during the next calendar year.

22. As a manufacturer of controlled substances, Ascent is required to register with DEA and maintain strict accounting for all distributions of Schedule I and II drugs.⁸

23. Under the CSA, a registrant must apply for individual procurement quotas on or before April 1 of the year preceding the calendar year for which the quota is being applied.⁹ In turn, DEA must respond to qualified applicants on or before July 1 of the year of the application (so, DEA should decide on the 2023 quota by July of 2022).¹⁰

24. Because 70% of Ascent's business involves manufacturing Schedule II controlled drugs, Ascent—like all other manufacturers and distributors of controlled substances—relies on DEA's timely approval of its quota applications to fulfil its work mandate and supply medications pursuant to customer contracts.

25. Upon receiving DEA's approval, Ascent acquires raw materials from several suppliers. Once Ascent produces the medications, it sells approximately 98% of its products to Camber Pharmaceuticals Inc. ("Camber"), a corporate affiliate with a common owner.

26. Camber does not take possession of any of the medications. Because it has no DEA registration, it uses a third-party agent, R&S Solutions, LLC (DEA Registration No.

⁸ Joseph T. Rannazzisi, Mark W. Caverly, *Drug Enforcement Administration Practitioner's Manual*, U.S. Dep't of Just. Drug Enf. Admin. Office of Diversion Control at 7, 16-17 (2006), https://www.in.gov/dhs/files/DEA_Practitioner_Manual.pdf.

⁹ 21 C.F.R. § 1303.12(b).

¹⁰ 21 C.F.R. § 1303.12(c).

RR0519934),¹¹ to distribute Ascent's drugs to down-stream drug-distribution companies and national pharmacies, such as Walgreens and CVS, and independent pharmacy groups.

B. Ascent's Quota Applications and the Ensuing Audits

27. In April and May 2022, Ascent submitted its quota applications for 11 different drugs for the 2023 Calendar Year (the "Quota Applications"). These applications included requests for quotas for Amphetamine (which is used to make generic Adderall) and Dexmethylphenidate, as well as Methylphenidate and Lisdexamfetamine (which are also prescribed to treat, among other things, ADHD). Procurement of these quotas are necessary to sustain Ascent's business, as well as to continue the supply of ADHD medications on which millions of patients rely. For context, Ascent had previously made up 20% of the market for generic ADHD medications.

28. Since May 3, 2022, DEA has conducted an extended regulatory inspection of Ascent. This inspection has included numerous site visits to Ascent by DEA during which DEA stated that it was conducting accountability audits and various recordkeeping reviews. During these various visits, DEA has purported to find discrepancies in some of Ascent's recordkeeping and inventory.

29. Ascent cooperated fully with the regulatory inspection, often producing thousands of documents within a few business days of requests.

30. In the meantime, various stakeholders—congresspeople, government agencies, and distributors—implored Ascent to accelerate its production of ADHD medications. In October 2022, the U.S. Food and Drug Administration ("FDA") acknowledged a nationwide shortage of

¹¹ R&S Solutions, LLC is a Tennessee corporation located at 96 American Drive, Suite 100A, Jackson, Tennessee 38301.

Adderall.¹² The bottleneck of brand name and generic-equivalent prescriptions has been linked to depression, withdrawal, and declines in learning and self-esteem.¹³

31. On September 22, 2022, a Senior Regulatory Review Officer at the FDA sent an email to Ascent indicating that FDA had received reports from doctors and patients regarding a shortage of certain ADHD medications. FDA asked whether Ascent had any supply of the products available. Ascent replied that it did not due to DEA's failure to issue a decision on its Quota Applications and requested that FDA inform DEA of the problem. On September 29, 2022, FDA emailed Ascent stating that it had relayed Ascent's concerns regarding the Quota Applications to DEA. On July 18, 2023 and August 28, 2023, FDA again sent an email to Ascent regarding reports of shortages of additional ADHD medications. Ascent again responded that they did not due to DEA's failure to issue a decision on its Quota Applications.

32. The Offices of Senator Sheldon Whitehouse and Senator Ron Wyden reached out to Ascent directly on May 18, 2023 and August 18, 2023, to inquire what Ascent could do about the shortage. Each time, Ascent was forced to reply that its hands were tied because of DEA's failure to respond to its Quota Applications.

33. Concerned about scarcity, Ascent beseeched DEA to grant its Quota Applications. Ascent asked for calls or meetings to address any DEA concerns numerous times, to no avail.

¹² See *FDA Announces Shortage of Adderall*, U.S. Food & Drug Administration (Updated Aug. 1, 2023), <https://www.fda.gov/drugs/drug-safety-and-availability/fda-announces-shortage-adderall>; see also, Christina Jewett, *F.D.A. Confirms Widespread Shortages of Adderall*, N.Y. Times (Oct. 13, 2022), <https://www.nytimes.com/2022/10/13/health/adderall-shortage-adhd.html>.

¹³ See Dani Blum, *Amid the Adderall Shortage, People With A.D.H.D. Face Withdrawal and Despair*, N.Y. Times (Nov. 16, 2022), <https://www.nytimes.com/2022/11/16/well/mind/adderall-shortage-withdrawal-symptomsadhd.html>.

Instead, DEA demanded tens of thousands of business records from Ascent. Ascent fully complied, making at least 6 document productions totaling more than 30,000 pages.

34. Thereafter, November 11, 2022, DEA finally revealed concerns to Ascent: DEA claimed that Ascent had problems with its recordkeeping.

35. None of these purported issues affected quality control of Ascent's manufacturing or suggested the possibility of diversion of controlled substances. Nevertheless, wanting to cure any gaps in its compliance programs, Ascent hired a nationally renowned expert, Krista Tongring of Guidepost Solutions, to conduct a thorough review of its compliance and recordkeeping practices. She promptly communicated her findings to DEA on September 15, 2023: Ascent's business records substantially complied with DEA laws and regulations and the physical security for the receipt, shipping, storage, handling, and manufacturing of controlled substances appeared to comply with DEA laws and regulations. True to form, DEA did not substantively respond.

36. During this period, DEA's inaction on the Quota Applications caused Ascent's operations to nearly halt as it began exhausting its supply of raw materials. DEA's inaction has devastated Ascent's business, causing a loss of 70% of projected revenues for 2023-2024. Ascent has also lost more than 100 employees. DEA stubbornly refused to render any decision on the quotas.

C. Without Options, Ascent Files Suit and DEA Retaliates

37. With no other options, on September 27, 2023, Ascent filed suit in this Court, *Ascent Pharmaceuticals, Inc. v. U.S. Drug Enforcement Administration*, No. 2:23-cv-07211 (E.D.N.Y. Sept. 27, 2023), seeking to compel DEA to decide the Quota Applications.

38. The next day, on September 28, 2023, DEA served Ascent with an Order to Show Cause, which sought to rescind Ascent's DEA registrations based on erroneous and exaggerated allegations of recordkeeping violations.

39. The following day, on September 29, 2023, DEA issued a decision denying the Quota Applications in their entirety (the “Quota Denial”). The Quota Denial stated:

In considering Ascent’s requests for quota, DEA’s Diversion Control Division received records pursuant to DEA’s authority under 21 CFR 1303.12(b) to request additional information that “may be helpful in detecting or preventing diversion.” After reviewing these records, **DEA lacks confidence in the data provided by Ascent in its quota requests**, a relevant “other factor” in reaching quota determinations pursuant to 21 U.S.C. 826(c).

Id. (emphasis added).¹⁴ DEA gave no other explanation. The letter did not mention any right or method to appeal the decision.

40. On October 4, 2023, Ascent filed an emergency motion for mandatory preliminary injunctive relief in the United States Court of Appeals for the Second Circuit. *See Ascent Pharmaceuticals, Inc. v. U.S. Drug Enforcement Administration*, No. 23-7246 (2nd Cir. Oct. 4, 2023). The DEA opposed the motion on October 16, 2023, and Ascent replied on October 23, 2023. The emergency motion remains pending.

41. At a subsequent status conference in the Administrative Proceeding, ALJ Wallbaum advised Ascent that if it intended to pursue a challenge under *Axon*, it should advise the tribunal as soon as possible by filing a motion for a stay along with a file-stamped copy of the complaint filed in district court.¹⁵

42. Ascent’s answer to the Order to Show Cause in the Administrative Proceeding is due November 8, 2023. A prehearing conference is scheduled for November 28, 2023.

¹⁴ Following receipt of the denial of its Quota Applications, Ascent voluntarily withdrew its Complaint on October 2, 2023.

¹⁵ Ascent will submit a file-stamped copy of this complaint with its motion for a stay in the Administrative Proceeding.

D. DEA Administrative Law Judges

43. DEA ALJs are officers for the purpose of Article II of the U.S. Constitution. DEA ALJs receive their appointments pursuant to the APA. Under that statute and its concomitant regulations, they preside over administrative proceedings, occupy a continuing office established by law, and exercise significant authority. For example, Sections 1316.52 and 1316.42(f) of Title 21 of the Code of Federal Regulations provide that ALJs shall oversee administrative proceedings. Section 930.204(a) of Title 5 of the Code of the Federal Regulations provides that DEA ALJs receive a career appointment and are exempt from probationary periods that apply to certain other government employees.

44. Similar to SEC ALJs, which the Supreme Court has held are inferior officers within the meaning of Article II, DEA ALJs enjoy broad discretion to exercise significant authority with respect to administrative proceedings. Under 5 U.S.C. § 556(c), DEA ALJs may, among other things:

- (1) administer oaths and affirmations;
- (2) issue subpoenas authorized by law;
- (3) rule on offers of proof and receive relevant evidence;
- (4) take depositions or have depositions taken when the ends of justice would be served;
- (5) regulate the course of the hearing;
- (6) hold conferences for the settlement or simplification of the issues by consent of the parties or by the use of alternative means of dispute resolution . . . ;
- (7) inform the parties as to the availability of one or more alternative means of dispute resolution, and encourage use of such methods;
- (8) require the attendance at any conference held . . . ;
- (9) dispose of procedural requests or similar matters;
- (10) make or recommend decisions . . . ; and
- (11) take other action authorized by agency rule consistent with the [APA].

45. DEA regulations also empower and require DEA ALJs to carry out adjudicative functions in hearings and resolve adversarial proceedings on behalf of DEA. In that regard,

Section 1316.52 of Title 21 of the Code of Federal Regulations provides that DEA ALJs are “to conduct a fair hearing, to take all necessary action to avoid delay, and to maintain order.” Under the same regulation, DEA ALJs have the additional authority and power to:

- (a) Arrange and change the date, time, and place of hearings . . . and prehearing conferences and issue notice thereof.
- (b) Hold conferences to settle, simplify, or determine the issues in a hearing, or to consider other matters that may aid in the expeditious disposition of the hearing.
- (c) Require parties to state their position in writing with respect to the various issues in the hearing and to exchange such statements with all other parties.
- (d) Sign and issue subpoenas to compel the attendance of witnesses and the production of documents and materials to the extent necessary to conduct administrative hearings pending before him.
- (e) Examine witnesses and direct witnesses to testify.
- (f) Receive, rule on, exclude, or limit evidence.
- (g) Rule on procedural items pending before him.
- (h) Take any action permitted to the presiding officer as authorized by this part or by the provisions of the [APA].

Id.

E. The DEA ALJ Appointment Process Violates the Appointments Clause

46. Section 3105 of Title 5 of the United States Code establishes the process for the appointment of all ALJs, including DEA ALJs. This statute provides that each federal executive agency “shall” appoint as many ALJs as necessary for the agency’s administrative proceedings.

47. On information and belief, DEA ALJs have at all times been appointed by the DEA Administrator.¹⁶ The DEA Administrator selects DEA ALJs from a pool of candidates that submit their applications to OPM. The DEA Chief ALJ reviews those applications and recommends certain ALJ candidates for consideration and appointment by the DEA Administrator.

¹⁶ Following the Supreme Court’s decision in *Lucia*, then-Attorney General Sessions “ratified” a number of ALJ appointments but ALJ Wallbaum was not yet an ALJ. Moreover, Ascent has found no public record of how or when she was appointed, with her own Chambers refusing to provide the information, *see supra* note 2.

48. On information and belief, ALJ Wallbaum, the DEA ALJ presiding over Ascent's Administrative Proceeding, was selected from a pool of candidates provided by OPM and appointed by the DEA Administrator upon recommendation from DEA's Chief ALJ.

49. The appointment of DEA ALJs by the DEA Administrator violates Article II's Appointments Clause because the DEA Administrator is not the "head" or "principal officer" of an executive department. DEA is not an executive department under Article II of the Constitution. Rather, DEA is an agency within and subordinate to the Department of Justice, an executive department of the United States.

50. The Attorney General of the United States is the head and principal officer of the Department of Justice. As the head of the Department to which DEA belongs, the power and authority to appoint DEA ALJs rests solely, in addition to the President, with the Attorney General. The DEA Administrator lacks the constitutional power and authority to appoint an ALJ.

51. Neither the President of the United States nor the Attorney General of the United States appoints ALJs to their positions at DEA. Thus, the DEA ALJs were appointed pursuant to a process that violates the Appointments Clause, a fundamental defect in the DEA's administrative enforcement process.

F. DEA's Scheme for the Removal of ALJs Violates Article II's Vesting of Executive Power in the President

52. The regulatory and administrative framework pursuant to which DEA ALJs may be removed also violates Article II because it robs the President and the Attorney General of their constitutional authority and duty to exercise executive power and to faithfully execute the laws of the United States through the oversight of inferior officers such as ALJs, including by removing them without cause.

53. The APA provides that ALJs, including DEA ALJs, may be removed only for good cause as established and determined by the Merit Systems Protection Board (“MSPB”). That statutory restriction renders the President and Attorney General unable to determine “good cause,” and thus unable to remove DEA ALJs without approval of the MSPB. Members of the MSPB themselves, however, may not be removed absent good cause. These dual for-cause removal limitations violate Article II under the Supreme Court’s ruling in *Free Enterprise*.

54. This needlessly complex removal structure violates Article II’s requirement that inferior executive officers not be protected from removal by their superiors at will, when those superiors are themselves protected from being removed by the President at will.

55. As alleged above, DEA ALJs are executive officers who exercise significant executive power. Nevertheless, (a) DEA ALJs are protected from removal by a statutory “good cause” standard, 5 U.S.C. §7521(a), and (b) MSPB members empowered to determine the “good cause” standard are themselves protected from removal by an “inefficiency, neglect of duty, or malfeasance in office” standard. 5 U.S.C. §1202(d). This arrangement thwarts the President’s Article II executive power and ensures that neither the President nor the Attorney General as Head of Department can take care that the laws are faithfully executed by determining whether good cause exists to remove inferior officers.

CAUSES OF ACTION

COUNT ONE

(Application for Injunctive Relief)

56. Ascent repeats and realleges each and every allegation in paragraphs 1-55 as if fully set forth here.

57. Without injunctive relief from this Court, Ascent will be required to continue to submit to an unconstitutional proceeding led by an unconstitutional decisionmaker which

constitutes a “here-and-now injury” that is “impossible to remedy once the proceeding is over, which is when appellate review kicks in” under *Axon*, 598 U.S. at 191. This, in and of itself, constitutes irreparable harm to Plaintiff unless the Administrative Proceeding is enjoined.

58. Furthermore, if the DEA Administrator, upon recommendation from the presiding DEA ALJ, finds that Ascent’s continued registration is against the public interest, the harm will be severe and irreversible. Ascent’s business will be forced to close its doors. Moreover, Plaintiff could not obtain meaningful judicial review in time to prevent this outcome. Nor can this harm be remedied after-the-fact with money damages, as numerous immunity doctrines would prevent Ascent from obtaining a financial damages award from DEA. And, in any event, Ascent will be out of business.

COUNT TWO
(Declaratory Judgment)

59. Ascent repeats and realleges each and every allegation in paragraphs 1-58 as if fully set forth here.

60. Ascent requests a declaratory judgment that the statutes, regulatory provisions, and policies providing for the appointment of DEA ALJs are unconstitutional as applied by DEA and DOJ.

61. Ascent further requests a declaratory judgment that the statutes, regulatory provisions, and policies providing for removal of DEA ALJs are unconstitutional as applied by DEA and DOJ.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for an Order and Judgment:

- (a) Declaring unconstitutional the statutes, regulatory provisions, and policies providing for the appointment and removal of DEA ALJs as applied by DEA and DOJ;
- (b) An order and judgment enjoining DEA and DOJ from carrying out an administrative proceeding against Ascent, including on the Order to Show Cause at issue or any other proceedings with regard to Ascent's DEA Ascent's DEA Certificates of Registration unless and until a constitutionally valid system is in place; and
- (c) Such other and further relief as this court may deem just and proper, including reasonable attorneys' fees and costs of this action.

Dated: New York, New York
November 7, 2023

Respectfully submitted,

WALDEN MACHT & HARAN LLP

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